

CLAIMS

1. A pharmaceutical composition, constituting a spray suspension comprising at least one liquid excipient and at least one solid excipient which essentially is insoluble in the liquid excipient, and at least one pharmaceutical active ingredient.
2. A pharmaceutical composition in accordance with claim 1, *characterised* in that the liquid excipient is a pressured aerosol propellant, such as dimethylether, butane, propane, mixtures of butane and propane, fluorinated hydro carbons, nitrogen, carbon dioxide and nitrous oxide.
3. A pharmaceutical composition in accordance with claim 2, *characterised* in that also water is included in the composition, preferably in a concentration between 10 – 95 w/w %, and more preferably in a concentration between 30 – 95 %.
4. A pharmaceutical composition in accordance with claim 1, *characterised* in that the liquid excipient is water or a mixture of water and an organic solvent, such as alcohols.
5. A pharmaceutical composition in accordance with anyone of claims 1-4, *characterised* in that the solid excipient consists of inorganic salts or polymers selected from the group consisting of natural polymers, modified natural polymers, synthetic polymers and mixtures thereof.

6. A pharmaceutical composition in accordance with claim 5, *characterised* in that the polymeric material consist of natural polymers selected from the group consisting of native cellulose, such as Cellulose I.
7. A pharmaceutical composition in accordance with claim 6, *characterised* in that the native cellulose is micro crystalline cellulose or milled qualities of micro crystalline cellulose.
8. A pharmaceutical composition in accordance with anyone of claims 1 to 7, *characterised* in that the excipient particles are suspended in the liquid excipient, wherein the active ingredient is either dissolved, partly dissolved or suspended in the liquid or precipitated on the surface of the solid excipient and where the excipient particles after actuation can form a matrix, in-situ, on the administration site, such as the skin.
9. A pharmaceutical composition in accordance with claim 8, *characterised* in that the composition also contains at least one additional solid excipient which is capable of retarding the drug release from the matrix formed in-situ.
10. A pharmaceutical composition in accordance with anyone of claims 8 and 9, *characterised* in that at least 50% by weight of the excipient particles have a particle size not less than 0.1 μm and where at least 90% by weight of the excipient particles have a particle size less than 50 μm .

11. A pharmaceutical composition in accordance with anyone of claims 1 to 7, *characterised* in that the excipient particles together with the active ingredient forms a plurality of larger individual particles (suspension particles).
12. A pharmaceutical composition in accordance with claim 11, *characterised* in that the excipient particles together with the active ingredient forms a plurality of larger individual particles that are porous and that the composition also contains at least one additional solid excipient which is capable of retarding the drug release from the suspension particles.
13. A pharmaceutical composition in accordance with anyone of claim 9 and 12, *characterised* in that the additional solid excipient is a polymer, with pronounced ductile properties thereby capable of reducing the porosity and/or average pore diameter of the suspension particles, or the matrix formed in-situ.
14. A pharmaceutical composition in accordance with anyone of claims 11-13, *characterised* in that the composition also contains at least one additional solid excipient which is capable of forming an outer membrane layer around the suspension particles, where the membrane layer retards the drug release and where the membrane layer is composed of non-polymeric or polymeric materials such as calcium phosphate, ethyl cellulose, methacrylate copolymer, polyamide, polyethylene, polyvinyl alcohol or polyvinyl acetate.
15. A pharmaceutical composition in accordance with anyone of claims 11-14, *characterised* in that at least 50% by weight of the

suspension particles have a particle size not less than 10 μm and where at least 90% by weight have a particle size smaller than 150 μm .

16.A pharmaceutical composition in accordance with anyone of claims 11-15, *characterised* in that the suspension particles have an essentially isodiametrical shape, and preferably the particles also have a smooth surface texture.

17.A method of preparing porous suspension particles comprising an active ingredient, in accordance with anyone of claims 11-16, *characterised* in that it comprises the steps of ;

- a. wet-milling or dry-milling the solid excipient(s) or a mixture of at least one active ingredient and a solid excipient(s) in a milling equipment inducing essentially compression and shear forces, resulting in fine particulate quality, where more than 90 % by weight is smaller than 5 μm and preferably smaller than 2 μm ; and
- b. drying and aggregating the product of step a. or the product of step a. with the addition of at least one active ingredient, in fine particulate form, by e.g. spray-drying or any other drying procedure possible, which will produce essentially isodiametrical aggregate particles.

18.A method of preparing porous suspension particles comprising an active ingredient, in accordance with anyone of claims 11-16, *characterised* in that it comprises the steps of ;

- a. porous excipient particles, excluding any active ingredient, are prepared in accordance with the method described in claim 17; and
 - b. at least one active ingredient is added to the product of step a. whereby the active ingredient is essentially positioned within the pore structure of the product of step a.
19. A method of preparing non-porous suspension particles (including an active ingredient), in accordance with anyone of claim 11 and claims 14-16, *characterised* in that the active ingredient is applied, by e.g. a coating process, as an outer layer on solid, non-porous, excipient particles.
20. A method of applying a drug release retarding outer membrane layer to the suspension particles, prepared in accordance with the method described in claims 17-19, and where the membrane layer is composed of non-polymeric-or polymeric materials such as calcium phosphate, ethyl cellulose, methacrylate copolymer, polyamide, polyethylene, polyvinyl alcohol or polyvinyl acetate.
21. Suspension particles obtainable by a method according to any one of claims 17 to 20.
22. A pharmaceutical preparation, utilising the composition in accordance with anyone of claims 1-16 or the suspension particles according to claim 21, *characterised* in that the preparation is a cutaneous spray, an ear spray or a nasal spray.

23. A pharmaceutical preparation, utilising the composition or the suspension particles in accordance with claim 22, *characterised* in that the preparation contains as the active substance, morphine, morphine sulphate, morphine hydrochloride, ketoprofen, lidocaine hydrochloride or other substances effective in the treatment of pain or capable of inducing anesthetic effect.
24. A pharmaceutical preparation, utilising the composition in accordance with anyone of claims 22 and 23, *characterised* in that the preparation is in the form of a pressurised aerosol or mechanical pump device.
25. A method for treatment of disorders, wherein to an individual afflicted with disorder is administered a pharmaceutical composition, constituting a spray suspension comprising at least one liquid excipient and one solid excipient which essentially is insoluble in the liquid excipient and at least one pharmaceutical active ingredient.
26. A method for treatment of disorders according to claim 25 wherein the drug release rate is controlled by varying the area of said composition covering the skin of an individual.
27. A method for treatment of disorders according to claim 26 wherein the drug release rate is controlled by using a device with a range of increasingly sized openings or a device with a diaphragm where the opening diameter can be varied.

28. A method for treatment of disorders according to claim 25 wherein the drug release duration is controlled by varying the height of said composition covering the skin of an individual.
29. A method for treatment of disorders according to claim 28 wherein the drug release duration is controlled by using a specific spraying time.
30. A method for treatment of disorders according to claim 25 wherein the drug release rate is controlled by varying the area of said composition covering the skin of an individual, and wherein the drug release duration is controlled by varying the height of said composition covering the skin of an individual.
31. A method for treatment of disorders according to claim 30 wherein the drug release rate is controlled by using a device with a range of increasingly sized openings or a device with a diaphragm where the opening diameter can be varied.
32. A method for treatment of disorders according to claim 30 wherein the drug release duration is controlled by using a specific spraying time.